NHS
National Institute for
Health Research

Clinical Research Network
Coordinating Centre

Study Portfolio and Recruitment: Initialise a New Study

User Guide

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Non Disclosure

This manual relates to:

Study Portfolio and Recruitment: Initialise a New Study.

Contents

Welcome to Study Portfolio & Recruitment

Study Portfolio & Recruitment is one of the applications in the UK CRN Portfolio Management System, hosted on the UKCRN Portal. Study Portfolio & Recruitment has been designed and developed to allow users to manage details of clinical studies on the UKCRN Portfolio and upload recruitment data relating to those studies, from any computer with internet access. It is a secure system; permission to manage study details and upload recruitment data is limited and password protected.

Purpose

This document guides you through the procedure that you should follow in order to initialise a new study on the UKCRN Portfolio.

Scope

This guide relates to the ‘Initialise a New Study’ process which is part of the Study Portfolio & Recruitment application in the UK CRN Portfolio Management System. The document is intended for users with ‘UKCRN Portfolio Manager’ or ‘Topic Portfolio Manager’ roles who wish to initialise a new study on the UKCRN Portfolio.

Assumptions

It is assumed that readers are existing UKCRN Portal account holders and have either ‘UKCRN Portfolio Manager’ or ‘Topic Portfolio Manager’ roles in the UK CRN Portfolio Management System.

Overview

This guide describes the steps required to create an initial record of a clinical research study on the UKCRN Portfolio.

Getting Started

The ‘Initialise a new study’ process is part of the **Study Portfolio & Recruitment** system hosted on the UKCRN Portal. You use this process to create an initial record of a clinical research study on the UKCRN Portfolio. A wizard guides you through the procedure.

Once a study has been initialised, the study information you have provided is stored in the system as a draft but is not released to the live UKCRN Portfolio database until further information is added and the study is approved. Only users with the appropriate permissions can initialise a new study.

Access Permissions

Before you can initialise new study on the UKCRN Portfolio, you must first have a UKCRN Portal account and either ‘UKCRN Portfolio Manager’ or ‘Topic Portfolio Manager’ roles.

If you do not have a UKCRN Portal account, you can sign up for one at https://portal.ukcrn.org.uk/login/. For more information, please refer to the UKCRN Web Portal User Guide. This can be accessed from the ***Help*** *link on the* ***UKCRN Portal Login*** *page (https://portal.ukcrn.org.uk/login/).*

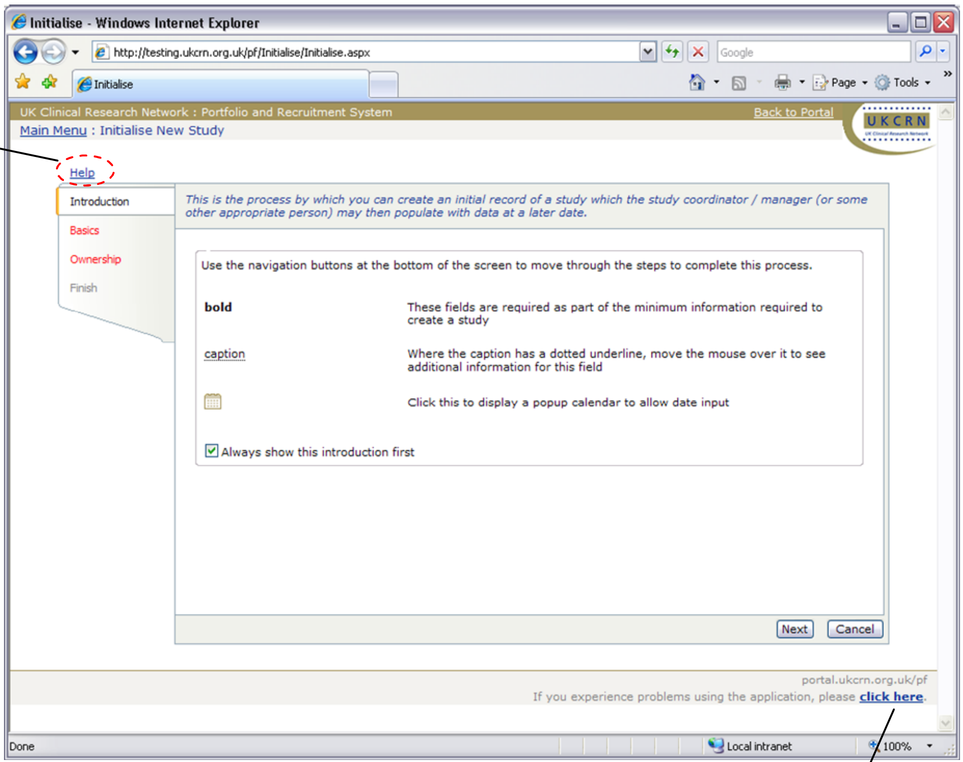
If you have a UKCRN Portal account, you can use ***My Profile*** *to request the required role. Access may not be immediate and may need to be validated. For more information, please refer to the My Profile User Guide. This can be accessed from the* ***User Guide and Videos*** *window in* ***My Profile****.*

Getting Help

Additional help resources are available. Click the **Help** link at the top left of the **Initialise a Study** wizard, above the tabbed menu. This will open the **UKCRN Help & User Guides** window from which you can access the *Initialise a New Study User Guide*. This provides step-by-step guided assistance through the steps required to create an initial record of a clinical research study on the UKCRN Portfolio. The user guide is in PDF format.

Click or **Close this window** to close the **UKCRN Help and User Guides** window.

Click **Help** to access the user guide and other help items.



Click to submit a query to the NIHR Service Desk.

If you wish to submit a query to the NIHR Service Desk, click the **click here** link displayed at the bottom right of any page. A **New Request** page opens. Enter the appropriate details and click **Submit Request**.

Timing Out

For security reasons, if you leave the **Study Portfolio & Recruitment System** inactive for 20 minutes or more, the system automatically logs you out. You must re-enter your log in details to regain access.

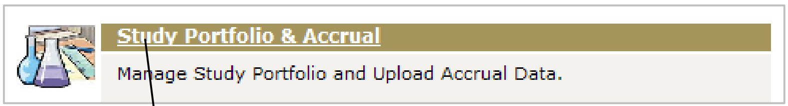
*If you are logged out of **Study Portfolio & Recruitment** before completing study initialisation, any data you have entered in the **Initialise a New Study** wizard will be lost.*

Initialising a New Study

Opening the Initialise a Study Wizard

1. Sign in to the UKCRN Portal in the usual way. Your **UKCRN Portal Home** page opens.

2. Click **Study Portfolio & Accrual**.

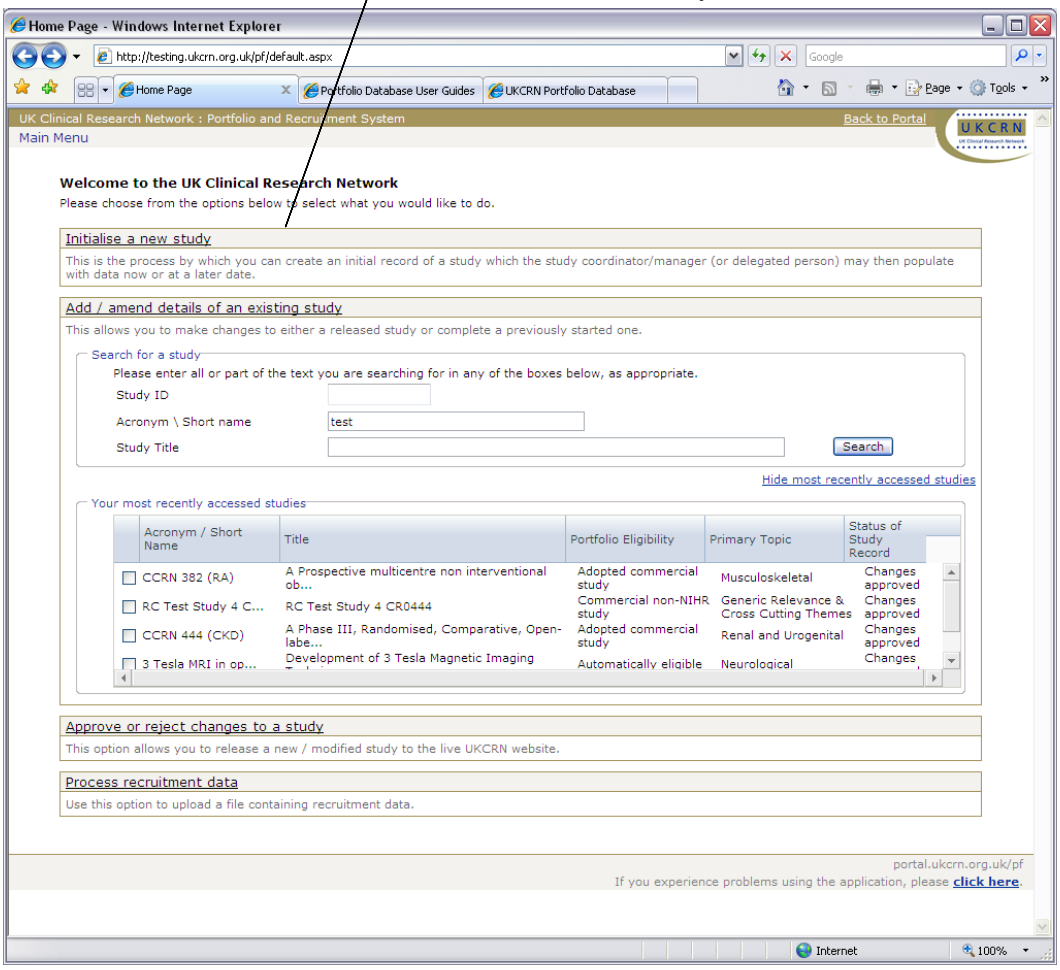


Click to open **Study Portfolio & Accrual**.

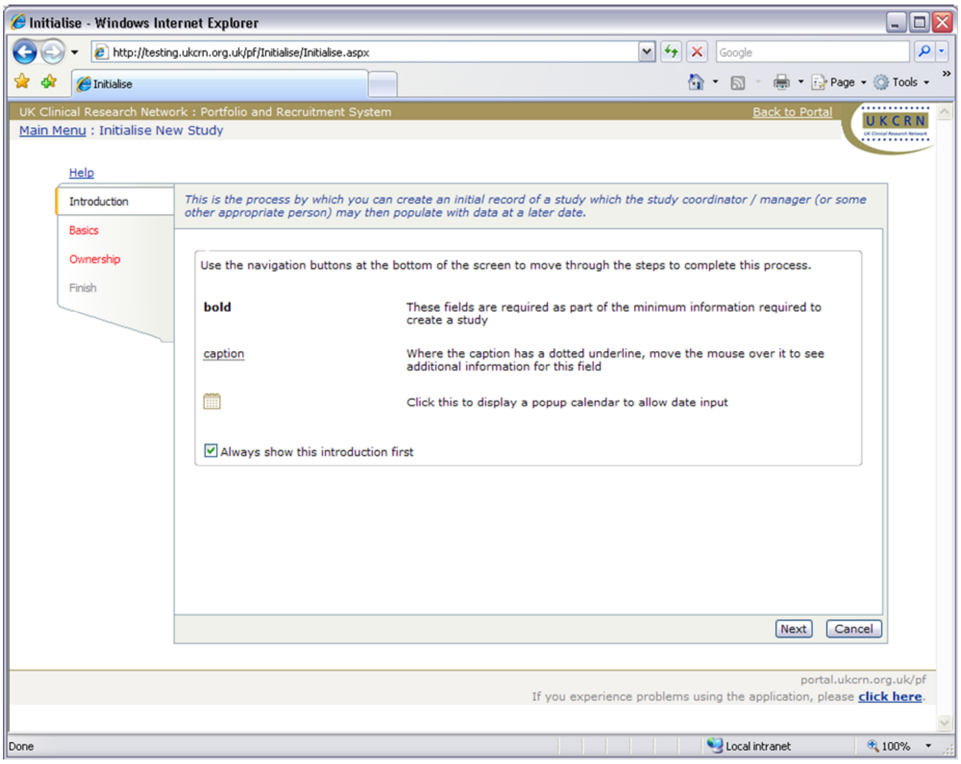
Your **Portfolio and Recruitment System** home page opens.

3. Click **Initialise a new study**.

Click **Initialise a new study**.



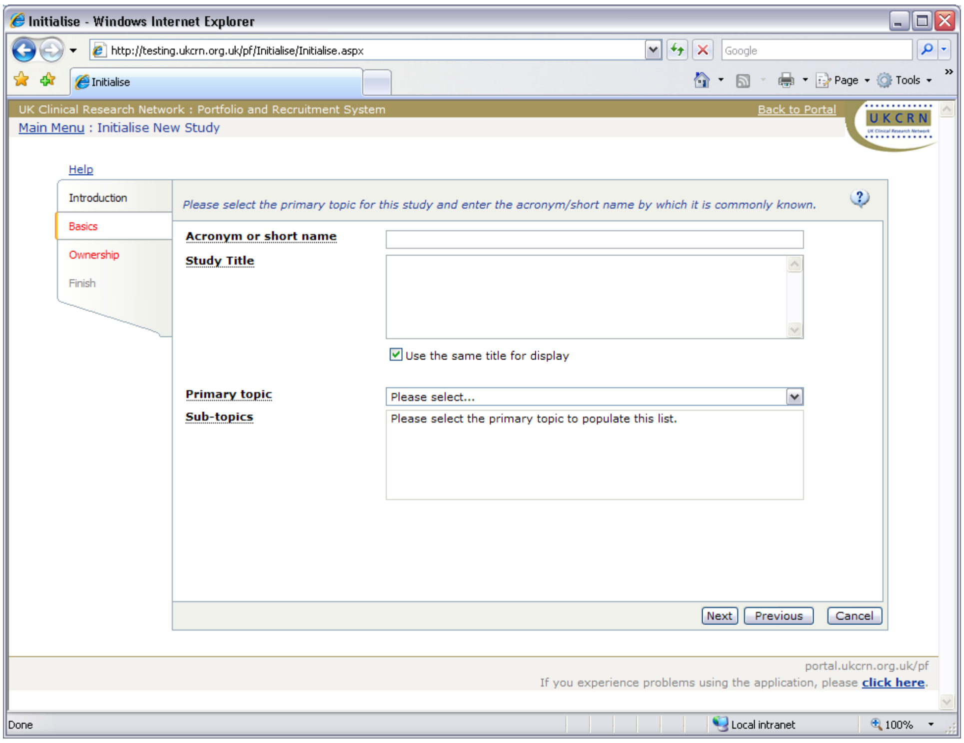
The **Initialise a New Study** wizard opens. The **Introduction** page is the first page you see when you open the **Initialise a New Study** wizard for the first time. This page provides information on the different types of fields and how to move through the steps to complete the process.



*If you do not want this page to be displayed the next time you initialise a new study, uncheck the **Always show this introduction first** box.*

4. Click **Next** at the bottom of the page, or **Basics** in the tabbed menu at the left hand side of the page. The **Basics** page is displayed.

The Basics Page



1. Fill out all fields on this page. Advice on completing the **Basics** fields is given below.

Field Name	Description
Acronym or short name	This name is displayed on the study's record in the UKCRN Portfolio and public Portfolio database. The acronym or short name must not exceed 100 characters (including spaces). The name will be checked to ensure that no studies with the same short name / acronym exist on the UKCRN Portfolio. **This is a required field**.
Study title	This name is used as the title for the study's record in the UKCRN Portfolio and public Portfolio database. It is the title of the study as it appears on the study protocol. The study title must not exceed 500 characters (including spaces). **This is a required field**.
Display Title	This field only appears if you un-tick the **Use the same title for display** checkbox. This is a shortened title that will appear as the title for the study record in the public Portfolio database instead of the **Study Title**. The text you type here should not exceed 500 characters (including spaces). **This is an optional field**.
Primary topic	This is the main or owning topic to which the study belongs. Please select only one primary topic. Studies can be jointly supported under a second topic at a later stage. **This is a required field**.
Sub-topics	This is the sub-topic under whose remit the study falls. You must specify a primary topic before you can select a sub-topic. Please select only one sub-topic at this stage; other sub-topics can be added after initialisation. **This is a required field**.

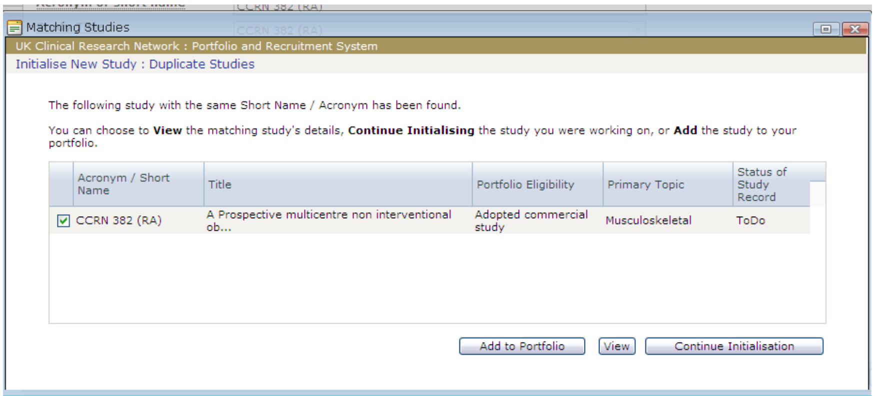
Once you have completed all the fields in this section, the **Basics** tab changes from red to black.

*If the **Basics** tab does not change from red to black on completing the final field not all the required fields have been filled in. A study cannot be initialised until all required fields are completed. Please review the details on this page and ensure all required fields are populated. These are highlighted in bold.*

2. Click **Next** or **Ownership** in the tabbed menu.

The **Ownership** page is displayed.

*If the **Matching Studies** window opens when you click **Next**, a study with the same **Short Name / Acronym** already exists in the Portfolio database. All studies with the same **Short Name / Acronym** are listed in this window:*



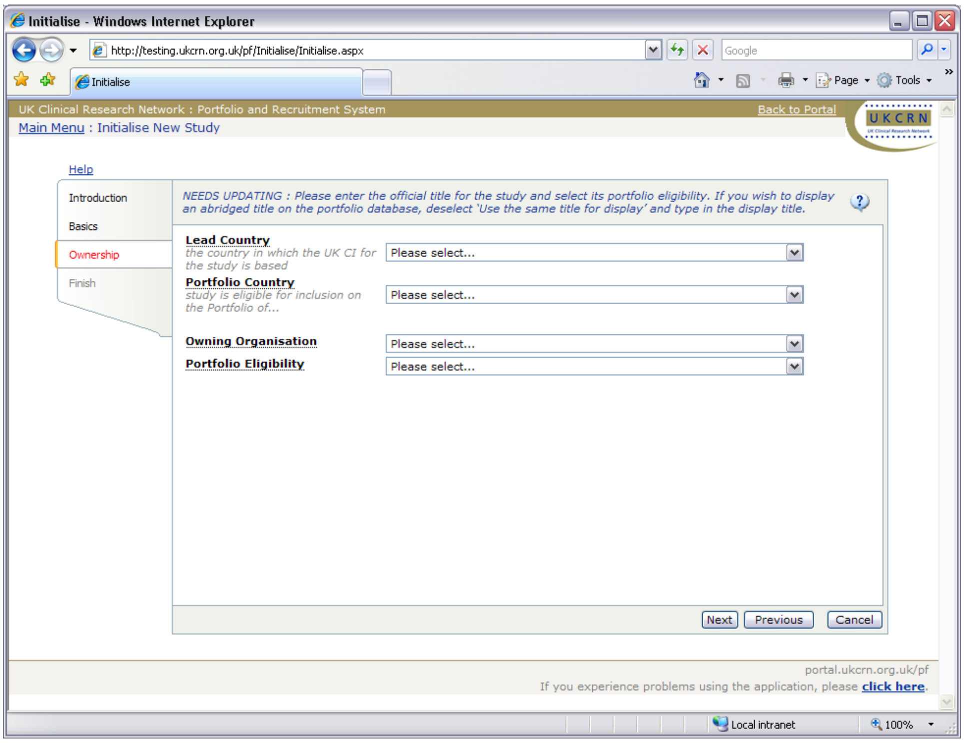
*If the study is not a duplicate, click **Continue Initialisation**. Type an alternative short name or acronym in the **Short Name / Acronym** field and click **Next** to continue.*

*To view a matching study's details, check the box next to the required study and click **View**.*

*To add a matching study to your portfolio, check the box next to the required study and click **Add to Portfolio**.*

***Add to Portfolio** is only displayed if the matching study belongs to a different topic. If you select this option, an email will be sent to the Study Coordinator or Topic Portfolio Manager for the owning topic requesting that this study be added to your portfolio. If the study is added to your portfolio, you will have read-only access to the data.*

The Ownership Page



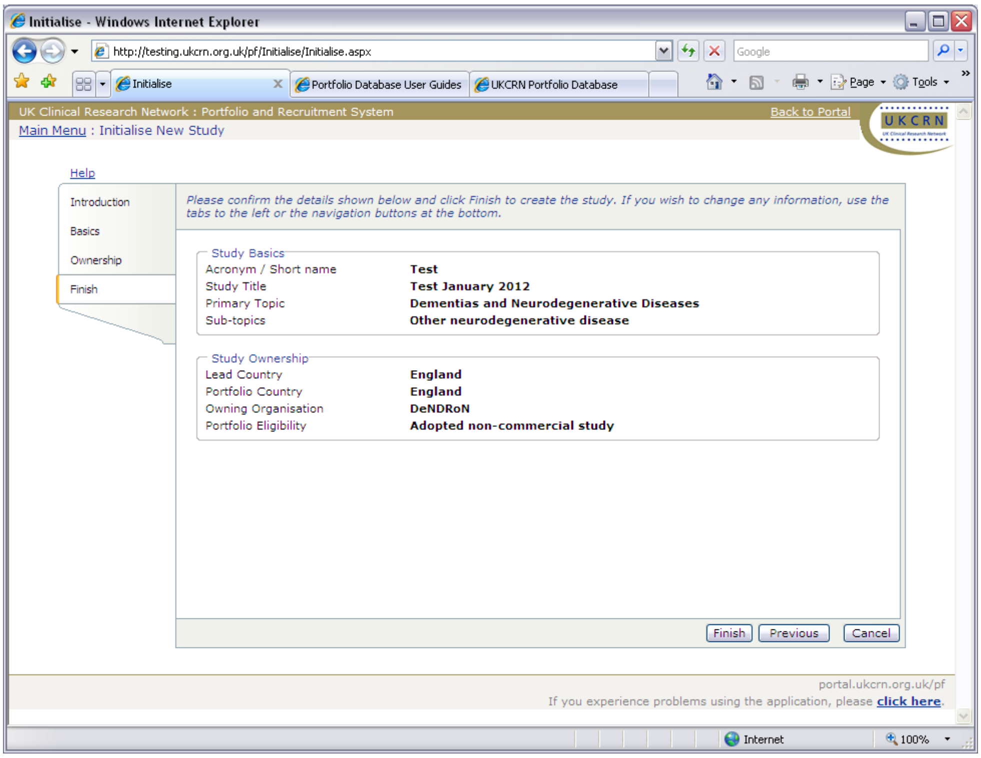
1. Fill out all fields on this page. Advice on completing the **Ownership** fields is given below.

Field Name	Description
Lead Country	This is the country where the study's UK Chief Investigator is based. You can choose only one country; the lead country can be changed at a later stage if necessary. **This is a required field**.
Portfolio Country	This is the country for whose portfolio this study is eligible. You can choose only one country; the portfolio country can be changed or additional countries added at a later stage. **This is a required field**.
Owning Organisations	This is the name of the main or owning organisation for this study. You can choose only one organisation. Other organisations can be added at a later stage, but the main owning organisation cannot be changed. **This is a required field**.
Portfolio Eligibility	Indicate the reason why the study qualifies to be included on the UKCRN Portfolio. **This is a required field**.

The **Ownership** tab changes from red to black, indicating all required fields have been completed.

2. Click **Next** or click **Finish** in the tabbed menu. The **Finish** page is displayed.

The Finish Page



The **Finish** page provides a summary of the study details you have entered.

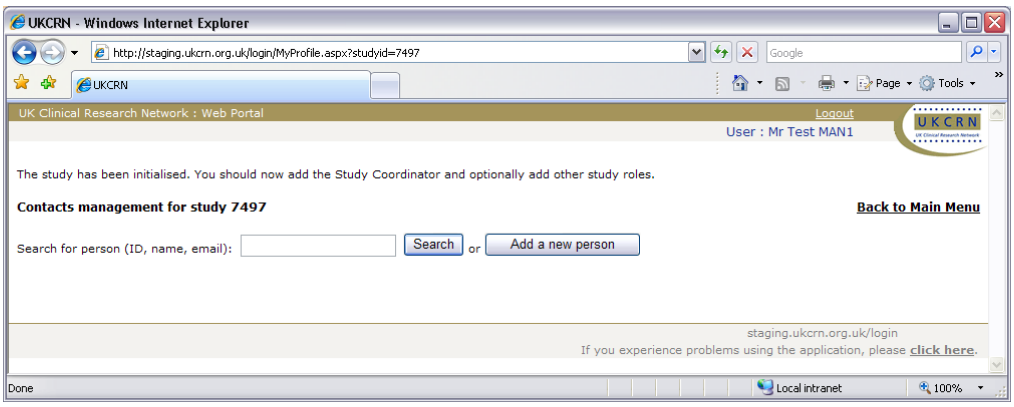
1. Check the details you have entered are correct.

> *If you wish to change any details, use the tabbed menu on the left side of the page to go directly to the appropriate page. You can also use the **Next** and **Previous** navigation buttons at the bottom of the page to move between pages.*

2. Click **Finish**.

The study is initialised and is added to the system as a draft. The study will not be available on the live UKCRN Portfolio database until further study details are added and the study has been approved by the appropriate Topic Portfolio Manager.

The **Contacts Management** page opens.



Contacts Management

You use the **Contact Management** page to specify the study contacts and assign study-based roles to them. You can choose to specify all or some of the study contacts now or at a later date.

If you do not wish to specify any study contacts now, click **Back to Main Menu** to return to the UKCRN Portal Home page or **Logout**, to log out of the UKCRN Portal. You can specify the study contacts at a later date by opening the required study in the **Modify a Study** wizard and clicking the **Contacts Management** button in the **Contacts** field on the **Contacts** page. For more information on this, please refer to the *Contacts Management User Guide.* This can be accessed from the **User Guides and Videos** link on the **Contacts Management** page.

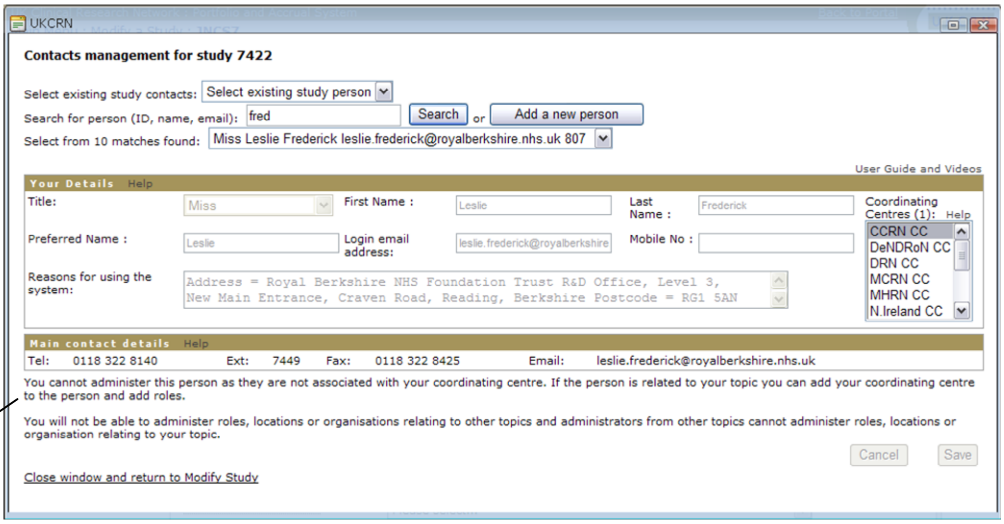
The Study Coordinator will be unable to access this study or add further details until you have assigned them the 'Study Coordinator' role.

Access Permissions in Contacts Management

Access to a person's details within **Contacts Management** depends on your role type. There are two types of access: read only access and full access. These are further explained below.

Read-Only Access

You have 'read-only' access to a person's details if you have a 'Topic Portfolio Manager' role, and the person you wish specify as a study contact is not associated with the topic you administer. Here is an example:



If the person you wish to specify as a study contact is not associated with the topic you administer, you have read-only access to their **Main Details** (except the **Coordinating Centres** field) and **Main Contact Details**. You also cannot view their organisations, locations or roles.

To gain full access to this person you must associate them with the topic you administer. To do this:

1. In the **Coordinating Centres** field, use **CTRL + left click** to select the coordinating centre relating to your topic.

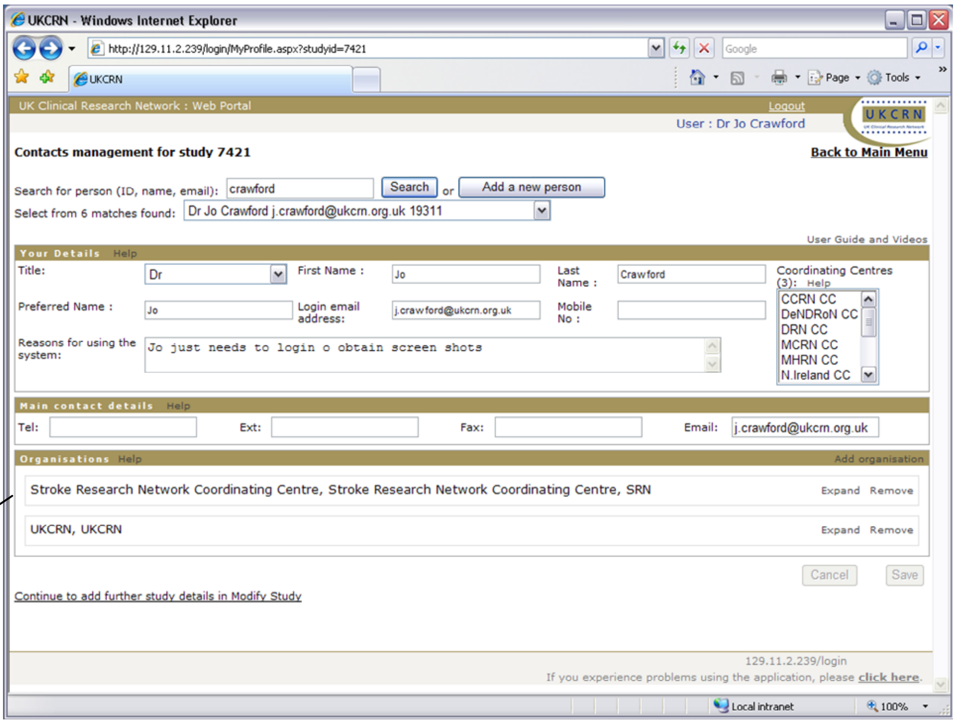
   *It is important you use the CTRL key. If not, any coordinating centres selected this field that are not yet associated with a role will be deselected and removed from the user's account when you click **Save**.*

2. Click **Save**.

You can now assign the required study role to this person.

Full Access

You will have full access to a person's details if you have either a UKCRN Portfolio Manager' role, or a 'Topic Portfolio Manager' role and the person you wish to specify as a study contact is associated with the topic you administer. Here is an example:



If the person you wish to specify as a study contact is associated with the topic you administer, you have full 'read-write' access to their main and contact details, organisations, locations and roles.

Adding a Contact to a Study

To add a contact to a study:

1. In the **Search for a person (ID, name, email)** box, type the ID number, name or email address of the person you wish to add.

2. Click **Search**.

3. If more than one match is found, click in the **Select from X matches found** box and select the required person from the dropdown list. The person's details are displayed below.

   –OR–

   If you cannot see the required contact in the list, the person you require does not exist on the system. To add a new contact to the system, please refer to *Adding a New Person*, page 16.

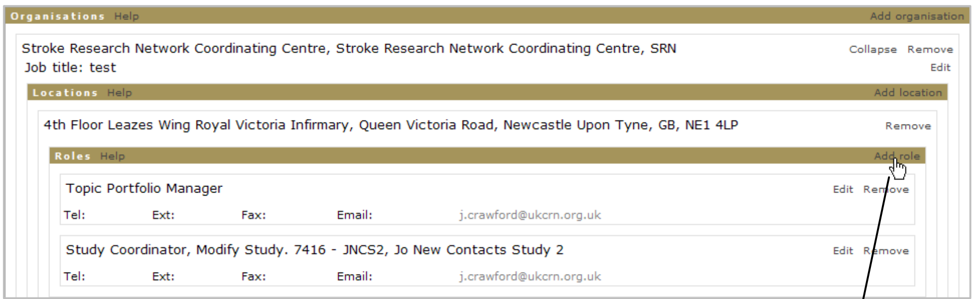
4. In the **Organisations** section, locate the organisation to which the study and intended role relates.

   If you cannot see the person's organisations, you do not have permissions to access this person. Please follow the instructions in Read-Only Access, page 13 to gain access.

   If the required organisation is not listed, it must first be added and the relevant location assigned to it before a role can be given. To do this, please refer to the My Profile User Guide. This can be accessed from the ***User Guide and Videos*** *window in* ***My Profile***

5. Click **Expand**, to the right of the organisation to view the person's locations and roles there.

6. Find the location where the role will be performed and, on the **Roles** bar immediately below this location, click **Add role**.



Click **Add role** to add a role at this location.

   If you cannot see the ***Roles*** *bar, you must first assign the role's location to the organisation. To do this, please refer to the My Profile User Guide. This can be accessed from the* ***User Guide and Videos*** *window in* ***My Profile****.*

7. Click in the **Select role** box and choose the appropriate role.

   The role is automatically validated and added to the **Roles** section.

   If you have assigned this role to a new organisation and location (i.e., one that did not previously exist in the Portfolio database), the role will be pending until the organisation and location have been validated by the NIHR Service Desk.

8. Click **Save**.

   The specified person will now have the appropriate access to this study in the **Study Portfolio & Recruitment** application.

9. Choose one of the following:

   - If you wish to open the **Modify a Study** wizard to continue adding study details, click **Continue to add further study details in Modify Study** at the bottom left of the page.

     The **Modify a Study** wizard opens with the study details. See the *Add / Amend Details of an Existing Study User Guide* for more details on how to proceed. This can be accessed from the **Help** link located above the tabbed menu in the **Modify a Study** wizard.

   - If you do not wish to add any further study details, click **Back to Main Menu** to return to the UKCRN Portal Home page or **Logout**, to log out of the UKCRN Portal.

Adding a New Person

To add a new person:

1. First check that the person you wish to add does not already exist in the Portfolio contacts system by following steps 1 to 3 in *Adding a Contact to a Study*, page 14.

2. If the person does not exist, click the **Add a new person** button.

3. In the **Main Details** section, type the persons details in the boxes provided.

   *If the **First Name** and **Last Name** you type match the first and last names of an existing contact, the following message will appear in red: 'There is an account already registered with similar details'. Check if this person already has a UKCRN Portal account. If not, continue with adding the person.*

   *If the **Login email address** you type matches that of an existing person, the following message will appear in red: 'There is already an account with these details'. The **Login email address** field will be cleared. If this happens, it is likely this user already has a UKCRN Portal account.*

4. From the **Coordinating Centres** list, choose the coordinating centre relevant to the topic you administer.

5. If you have permissions to administer industry and non-industry users, the **Type** box will be visible beneath the **Reasons for using the system** field. Click in this box and select the appropriate person's type.

6. In the **Main Contact Details** section, enter the person's telephone, extension and fax numbers in the appropriate boxes.

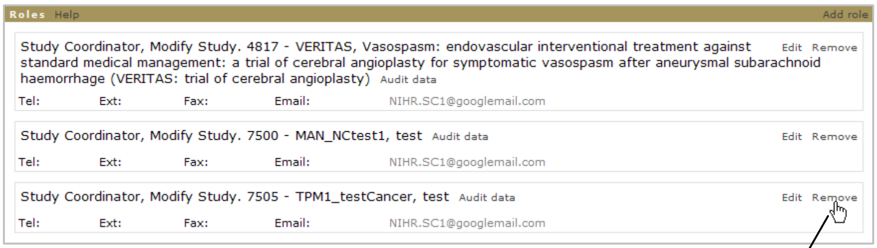
7. Assign the appropriate organisations and locations to this person. For more details on how to do this, please refer to the *My Profile User Guide*. This can be accessed from the **User Guide and Videos** window in **My Profile**.

You can now assign a study-based role to this person. To do this, please follow the instruction in steps 4 to 8, *Adding a Contact to a Study*, page 15.

Removing a Study Contact's Role

If you inadvertently assign an incorrect study role, you can remove it and reassign the correct role. To remove a study contact's role:

1. Locate the required role and click **Remove** to the right of the role.



Click **Remove**.

2. Click **Save**. The role is removed.

Appendices

Glossary

TERM	DEFINITION
CC	Coordinating Centre.
Chief Investigator	A ‘role’ associated with access permissions in the UK CRN Portfolio Management System. Users with this role can access the ‘Add / Amend details of an existing study’ process in Study Portfolio & Recruitment for their defined study.
My Profile	One of the applications in the UK CRN Portfolio Management System. My Profile allows all UKCRN Portal account holders to view and manage their portal account details, view existing access permissions and request new permissions to access applications within the UK CRN Portfolio Management System.
NIHR CRN	National Institute of Health Research Clinical Research Network. The NIHR CRN is managed by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) and is one of the four networks that comprise the UK Clinical Research Network.
Public Portfolio Database	This is a small set of publically available approved study information from the live UKCRN Portfolio database. No specific permissions are required to access this; any user can search this database for studies on the UKCRN Portfolio using the Portfolio Search Tool, http://public.ukcrn.org.uk/search/.
Record Administrator	A ‘role’ associated with access permissions in the UK CRN Portfolio Management System. Users with this role can access the ‘Add / Amend details of an existing study’ process in Study Portfolio & Recruitment for their defined study.
Role	Level of permission for access to specific applications within the UK CRN Portfolio Management System.
Study Coordinator	A ‘role’ associated with access permissions within the UK CRN Portfolio Management System. Users with this role can access the ‘Add / Amend details of an existing study’ process in Study Portfolio & Recruitment for their defined study.
Study Portfolio & Recruitment	One of the applications in the UK CRN Portfolio Management System. Study Portfolio & Recruitment allows users with the appropriate access permissions to manage details of clinical studies on the UKCRN Portfolio and upload recruitment data relating to those studies.
TCRN	Topic Clinical Research Network.
Topic	A specific disease area for research. Examples of topics include cancer, stroke, blood, skin, diabetes etc.

TERM	DEFINITION
Topic Portfolio Manager	A ‘role’ associated with access permissions in the UK CRN Portfolio Management System. Users with this role can access all aspects of Study Portfolio & Recruitment for studies within their defined topic.
UKCRN	United Kingdom Clinical Research Network.
UKCRN Portal	A web page that provides access to the core applications within the UK CRN Portfolio Management System.
UKCRN Portfolio	A national database of clinical research studies which meet specific eligibility criteria. The UKCRN Portfolio comprises the NIHR CRN Portfolio in England, the Northern Ireland Clinical Research Network Portfolio, the Scottish Clinical Research Network Portfolio and the Clinical Research Collaboration Cymru Portfolio. Most study information is password protected and only available to staff working on UKCRN Portfolio studies.
UK CRN Portfolio Management System	The suite of applications used to manage details and activities of studies on the UKCRN Portfolio. The application suite includes My Profile, Study Portfolio & Recruitment, Industry Study Portfolio, Reports, Validate Roles, Validate Organisations and Locations, People Administration, Local Portfolio Management System (LPMS) and Local Research Network Finance.
UKCRN Portfolio Manager	A ‘role’ associated with access permissions in the UK CRN Portfolio Management System. Users with this role can access all aspects of Study Portfolio & Recruitment for all studies and topics.

Feedback

Please report any problems you encounter with Study Portfolio and Recruitment: Initialise a New Study. If you experience any problems using the application, please contact the NIHR Service Desk Team via the link displayed at the bottom right corner of the screen.

Please give as much detail as you can about the nature and circumstances of the problem.

Document Control

The controlled version of this document is maintained electronically and accessed via the **Help** link in the **Initialise a Study** wizard and the NIHR CRN CC website (http://www.crncc.nihr.ac.uk/resources/systems_user_guides). If you are reading this in printed form or as a local copy, you should refer to the **Initialise a Study** wizard or the website to ensure that you are using the latest version.

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Revision History			
Version	Date	Author	Comments
1.0	09 Dec 2011	JC	First version
1.1	19 Aug 2011	JC	Updated URLs to the Systems User Guides on the CRN CC website. Rebranded document. Please note that we have also started replacing the term “accrual” with the term “recruitment”. This work is still in progress and until all systems change over to the new terminology, the term “accrual” will continue to appear on parts of the Portfolio system.
1.2	19 Jan 2011	FM	Updated for CR0444 • Changes to **Portfolio Eligibility** field options

